24. With regard to the first practice - disseminating written information - the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use, and has provided the materials to the FDA prior to dissemination. The materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa (b) & (c); 360aaa-1.

25. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." Id. These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. Id. The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

26. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

B. Prescription Drug Reimbursement Under Federal Health Care Programs

27. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use will be reimbursed under Medicaid and other federal health care programs.

1. The Medicaid Program

28. Medicaid is a public assistance program providing payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

29. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." Id. §1396r-8(k)(3).

30. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or use of which is supported by one of the drug compendia identified in the Medicaid statute. Id. §1396r-8(k)(6). During the time period relevant to this Complaint, many of the off-label uses of drugs promoted by Cephalon and Takeda were not eligible for reim-

bursement from Medicaid because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute. Use of Provigil, for example, for treating fatigue associated with depression, use of Gabitril for fibromyalgia, post traumatic stress disorder, and insomnia, and use of Actiq on an outpatient basis for breakthrough pain other than cancer pain is not supported by the compendia as medically safe and effective, although Cephalon and Takeda have promoted the drugs for those and other uses in the ways set forth below.

31. Additionally, because Cephalon's and Takeda's unlawful off-label marketing efforts were designed to generate overutilization of their drugs in situations in which the drugs either were not proven safe and effective or were not medically necessary for treatment of patients' specific medical conditions, Cephalon and Takeda caused physicians to submit claims for reimbursement to Medicaid that were unwarranted and therefore false.

2. Other Federal Health Care Programs

32. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/ TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.

33. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. Coverage of

off-label drug uses under these programs is similar to coverage under the Medicaid program. See, e.g.,TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

34. During the time period relevant to this Complaint, the off-label uses of the Cephalon prescription drugs promoted by Cephalon and Takeda did not qualify for reimbursement under any of the various federal health care programs because there was inadequate approval or support for such drugs to be eligible for reimbursement and/or because defendants' unlawful marketing activities created overutilization of such drugs in situations where they were not medically necessary for treatment of patients' specific medical conditions.

3. The Anti-Kickback Statute

35. The federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are not medically necessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

36. The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, drug companies may not offer or pay any remunera- remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or

recommend drugs that may be paid for by Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, or any other federal health care program.

37. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company to a physician which has as one of its purposes inducement of the physician to write additional prescriptions for the company's pharmaceutical products.

38. Concern about improper drug marketing practices like those alleged in this Complaint prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994). Among the improper practices cited by the Inspector General were drug companies' payments to physicians where the physician had offered no particular services of benefit to the drug company but the payment appeared to have been based on the volume of business the doctor could generate for the drug company. Id.

39. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs. With regard to Medicaid, for example, each physician and pharmacist that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, these agreements typically require the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback provisions of the law. In Massachusetts and a number of other states, the Medicaid claim form itself contains a a certification by the provider that the provider has complied with all aspects of the Medicaid

program, including compliance with Federal laws. In sum, either pursuant to provider agreements, claims forms, or other appropriate manner, pharmacists and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

V. BACKGROUND FACTUAL ALLEGATIONS RELATING TO RELATOR'S ORIGINAL QUI TAM ACTION THAT SETTLED IN 2008

40. In the early days of its corporate existence, Cephalon used to take seriously legal restrictions on how it could market pharmaceuticals that it manufactured and/or distributed. Beginning in or about early 2000, however, as its development of the market for on-label use of its products began to mature, the company sought to achieve greater rates of growth and thus began focusing efforts on expanding its sales for off-label uses of its products. The company continued to pay lip service in its written materials to FDA's prohibitions against off-label marketing of prescription drugs, so as to give the false appearance of compliance. However, through oral directives and by altering its marketing program design Cephalon increasingly pressured its sales force to target inappropriate medical specialists and to meet ever-increasing sales quotas that it knew would require its sales force to market off-label uses of its products and to engage in kickbacks and other illegal remunerations in order to reach demanded levels of sales of each of the Cephalon prescription drugs.

A. Cephalon Illegally Promoted Provigil for Off-Label Treatments.

41. Until January 2004, Provigil's only on-label indication was for treatment of excessive daytime sleepiness associated with narcolepsy. In January 2004, the FDA approved Provigil for use in improving daytime wakefulness of patients suffering from obstructive sleep apnea/

hypopnea syndrome and shift work sleep disorder. Beginning not later than January 2000, however, Cephalon aggressively marketed Provigil for those conditions, as well as for continued off-label uses such as fatigue associated with depression, fatigue associated with multiple sclerosis, fatigue associated with schizophrenia, chronic fatigue, and for attention deficit hyperactivity disorder in children.

42. To encourage off-label marketing by its sales force, Cephalon de-emphasized sales calls to sleep specialists likely to be treating patients with on-label indications for use of Provigil and directed its sales representatives instead to concentrate their sales calls increasingly to psychiatrists whom Cephalon's research indicated were treating patients likely to suffer the kinds of disorders for which off-label prescriptions could be solicited. Such targeting was done, for example, with psychiatrists who prescribed substantial amounts of anti-depressant drugs, as a means of attempting to develop off-label sales of Provigil for fatigue associated with depression. Cephalon told its sales representatives that they should plan on visiting target physicians 8-10 times per year in order to achieve increased productivity of those physicians in writing new prescriptions for Cephalon drugs. Sales representatives who did not make a priority of calling on psychiatrists identified by Cephalon as likely candidates for off-label sales were verbally rebuked and/or financially punished for not pursuing those leads.

43. Cephalon also directly manipulated its bonus incentive program to encourage promotion of off-label sales. Prior to 2000, Cephalon's bonus incentive program contained terms designed to limit incentives for sales personnel who unlawfully marketed Cephalon prescription drugs for off label uses. Substantial off-label sales did not count toward fulfillment of sales representatives' sales quotas, and off-label sales were not a basis upon which quarterly bonuses

would be earned. In or about 2000, however, when Roy Craig was hired by Cephalon as Vice President of Sales Operations, and continuing until Relator's original case led to a 2008 settlement that precluded such arrangements, those constraints were removed. At Craig's direction, required sales quotas were substantially increased, and potential bonuses to be made from increased sales beyond quota levels were uncapped, all in an effort to encourage greater off-label marketing by Cephalon's sales representatives. In fact, sales quotas were raised so high that the only realistic way for sales representatives to reach required (pre-bonus) levels of performance was to increase off-label sales.

44. During this same period, oral presentations from upper management to sales representatives and managers at Cephalon's national and regional sales meetings became more openly disdainful of the FDA's stricture against off-label marketing. Ever-greater attention was directed during conferences to discussing techniques that could be applied by sales representatives when meeting with physicians to turn discussion to potential off-label uses of Cephalon's drugs without being too obvious about what was being done.

45. One technique used to achieve this goal was for sales representatives to bring up the putative mechanism of action (the actual mechanism of action for Provigil is not known, but sales representatives would discuss the suspected mechanism of action as if it were established) of their drugs to physicians orally and with visual aids, shepherd discussion to off-label medical conditions that might be addressed through the same mechanism of action, and ask the physicians if they had patients that might benefit from application of such a therapeutic approach to their conditions.

46. Cephalon-sponsored case studies were touted and made available to physicians by

sales representatives in support of the claimed off-label benefits. But such studies typically were retrospective analyses solicited by Cephalon from physicians who prescribed Provigil off-label and for whose patients the doctors believed the product showed promising effects. Such anecdotal, individual case observations were in lieu of control-group studies designed and executed to measure the efficacy of Cephalon's product compared to placebo treatment or no treatment at all.

47. Strategies also were developed to lure potentially large off-label prescribers to promotional activities dressed up as continuing medical education ("CME") opportunities. Among these strategies was the recruitment by Cephalon sales representatives in 2001 and 2002 of potentially high-prescribing physicians to attend national training sessions to become speakers for Cephalon's drugs at "Medical Education Programs" that were sponsored locally by the sales representatives. These three-or-four-day speaker training events were done on an all-expense-paid basis at luxury resort locations in Florida, California and Bermuda. Although pitched as presentations by independent experts, Cephalon in fact exercised substantial control over the programs, in violation of the FDAMA. It hired a psychiatrist, Steven Stahl, to make a presentation which it largely prepared and finally reviewed and approved, and which emphasized potential off-label applications of Cephalon's products. In addition, Cephalon sales representatives sometimes attended the presentations and made themselves available to answer questions that might arise about off-label use of Cephalon products. Indeed, such off-label questions were often "planted" by Cephalon representatives to appear to be unsolicited.

48. Potential "speakers" were chosen to attend speaker training events based on their potential market share as off-label prescribers of Cephalon products. Because they were

"trained" as an inducement to write off-label prescriptions, rather than because of any skill as public speakers, many were ill-suited actually to serve as speakers at local events and were never intended to be asked. Those that were asked to lead local Cephalon "Medical Education Programs" ("MEPs") were paid speaking fees from the budget of their local Cephalon sales representative to make dinner or lunch presentations to other physicians that Cephalon's sales representatives had identified as potentially significant off-label prescribers of Cephalon drugs. Such payments were made even if no other invited physicians actually attended the planned presentation. However, even good public speakers were dropped by Cephalon from those that would be hired to lead future Medical Education Programs if experience later showed that they did not themselves write substantial off-label prescriptions for Cephalon's products. In 2003, for for example, Relator's manager Joe Haygood instructed relator not to hire Dr. Weiss as a speaker at any future MEPs unless and until Dr. Weiss's personal prescription performance substantially improved.

49. Cephalon's local Medical Education Programs were offered as CME opportunities for the local physicians that the sales representatives identified to Cephalon's medical liaisons as promising sales leads to invite. Slide presentations presented at those meetings closely track the presentations made at the Steven Stahl training sessions, including the high level of attention paid to potential off-label uses doctors could make of Cephalon's drugs. As was true with Dr. Stahl's presentation, the local speakers' presentations were also largely prepared (and finally reviewed and approved) by Cephalon's sales representatives, who attended the sessions and answered questions regarding off-label use. Indeed, at one such event in 2003, Phil Tocco, the sales manager for Cephalon's Pittsburgh office, completely supplanted the physician speaker in